FDA Adverse Reaction Reporting System for Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)

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FDA's Reporting Requirement: 21 CFR Part 1271.350-Effective May 25, 2005

- Manufacturers must ***investigate:***
  - ***Any*** adverse reaction involving a communicable disease related to an HCT/P that they made available for distribution.
- Manufacturers must ***report*** to FDA
  - An adverse reaction involving a communicable disease if it:
    - Is fatal
    - Is life-threatening
    - Results in permanent impairment of function or permanent damage to body structure; or
    - Necessitates medical or surgical intervention, including hospitalization.

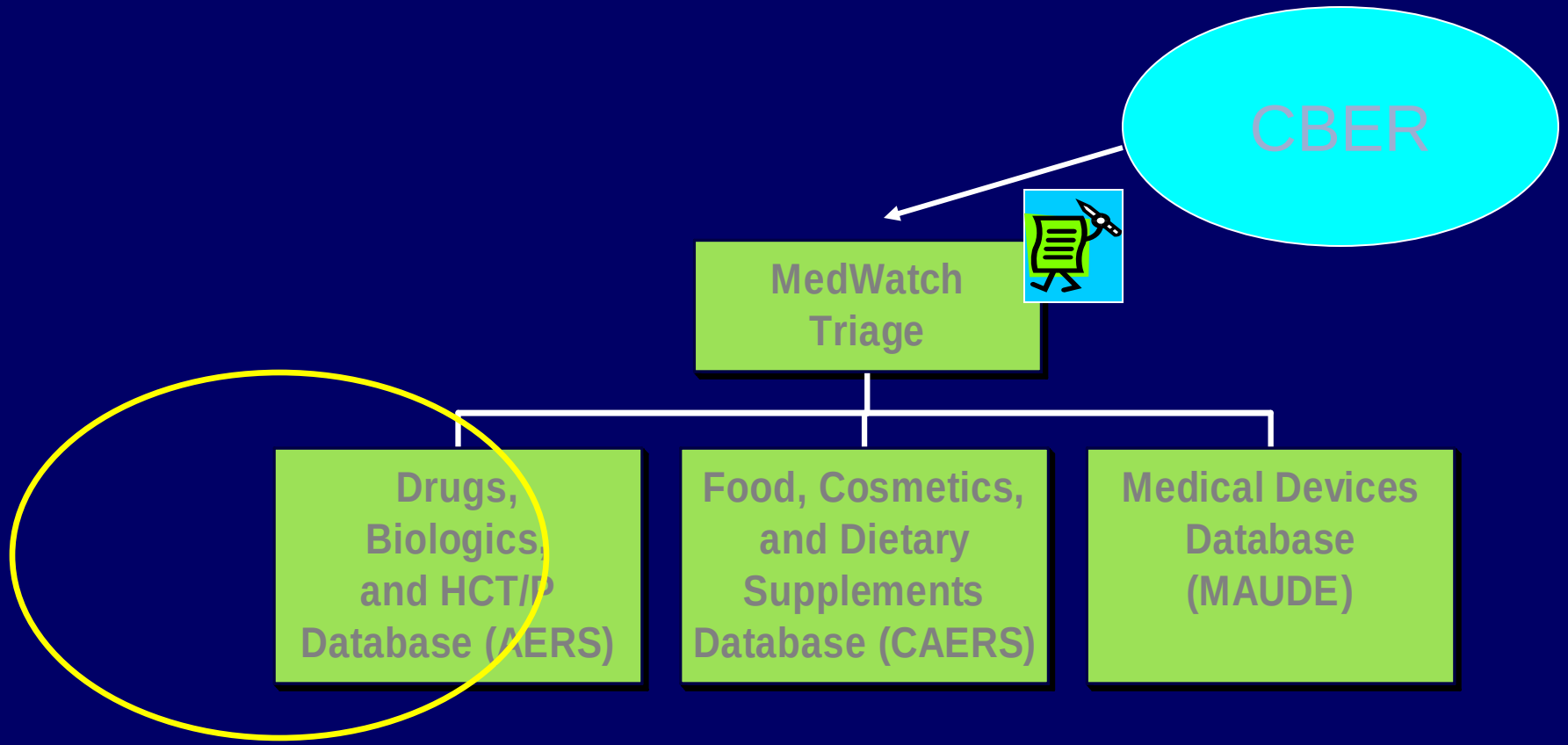
FDA's Reporting Requirements

- *Adverse reaction* means a noxious and unintended response to any HCT/P for which there is a reasonable possibility that the HCT/P caused the response
- To report adverse reactions to FDA, manufacturers must submit a MedWatch 3500A to FDA within 15 days of receipt of information
- And provide follow-up within 15 days of receipt

How are Adverse Reactions Reported to FDA?

- For Manufacturers:
  - Use Form FDA 3500A (Medwatch)
  - Have 15 days from receipt of information
- For Voluntary reporters
  - Use Form FDA 3500 (Medwatch)
  - Also promptly report to HCT/P establishments
- FDA Medwatch reporting system
  - http://www.fda.gov/medwatch

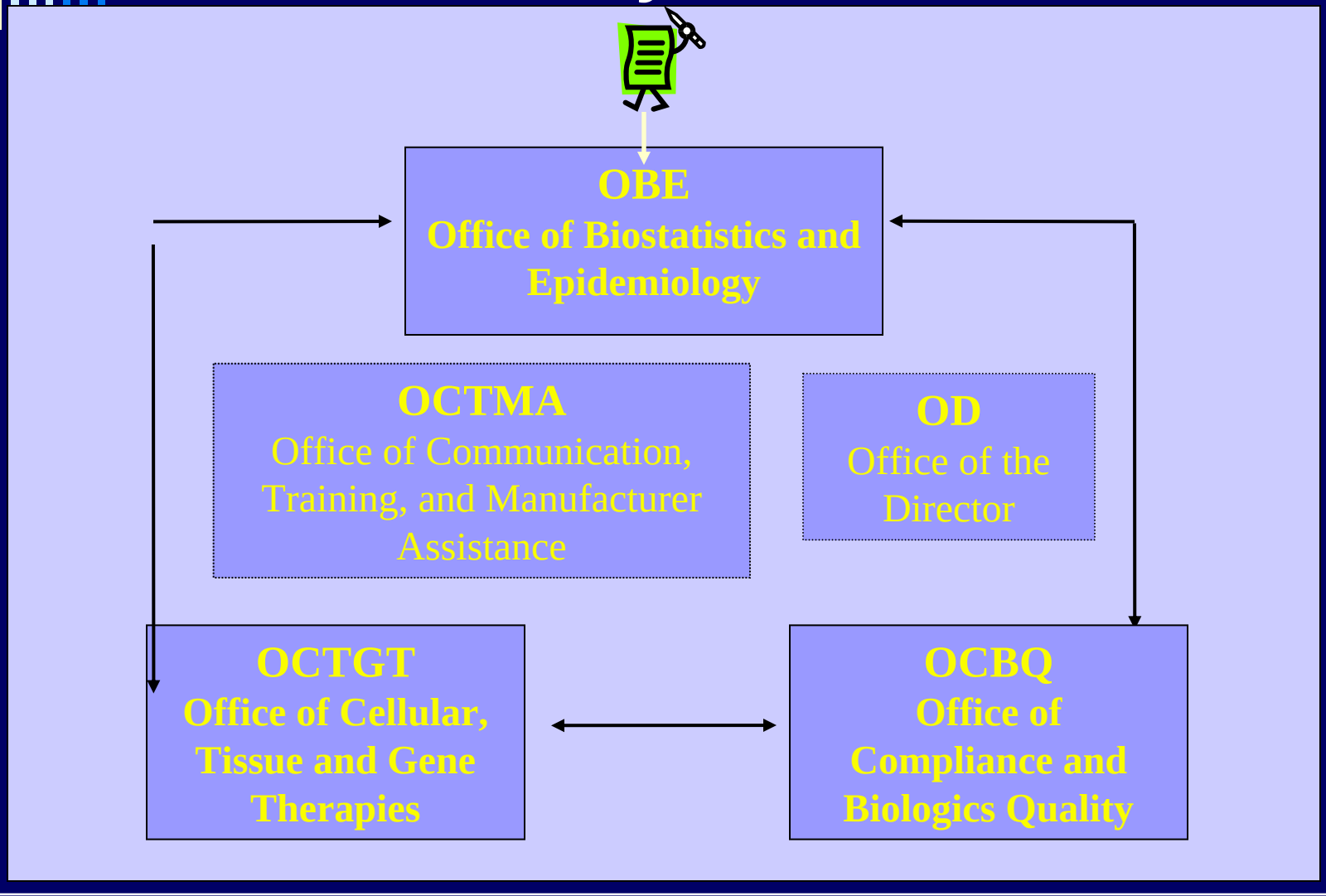
The Journey:
MedWatch Form Triage



Tissue Safety Team (TST)

- Consists of CBER representatives from four CBER offices and the Center Director's Office
- Coordinates with CDC, FDA District Offices, Center for Devices, etc as needed
- Purpose is to coordinate responses to reports of HCT/P adverse reactions and to develop procedures to facilitate rapid and comprehensive responses by FDA

Tissue Safety Team



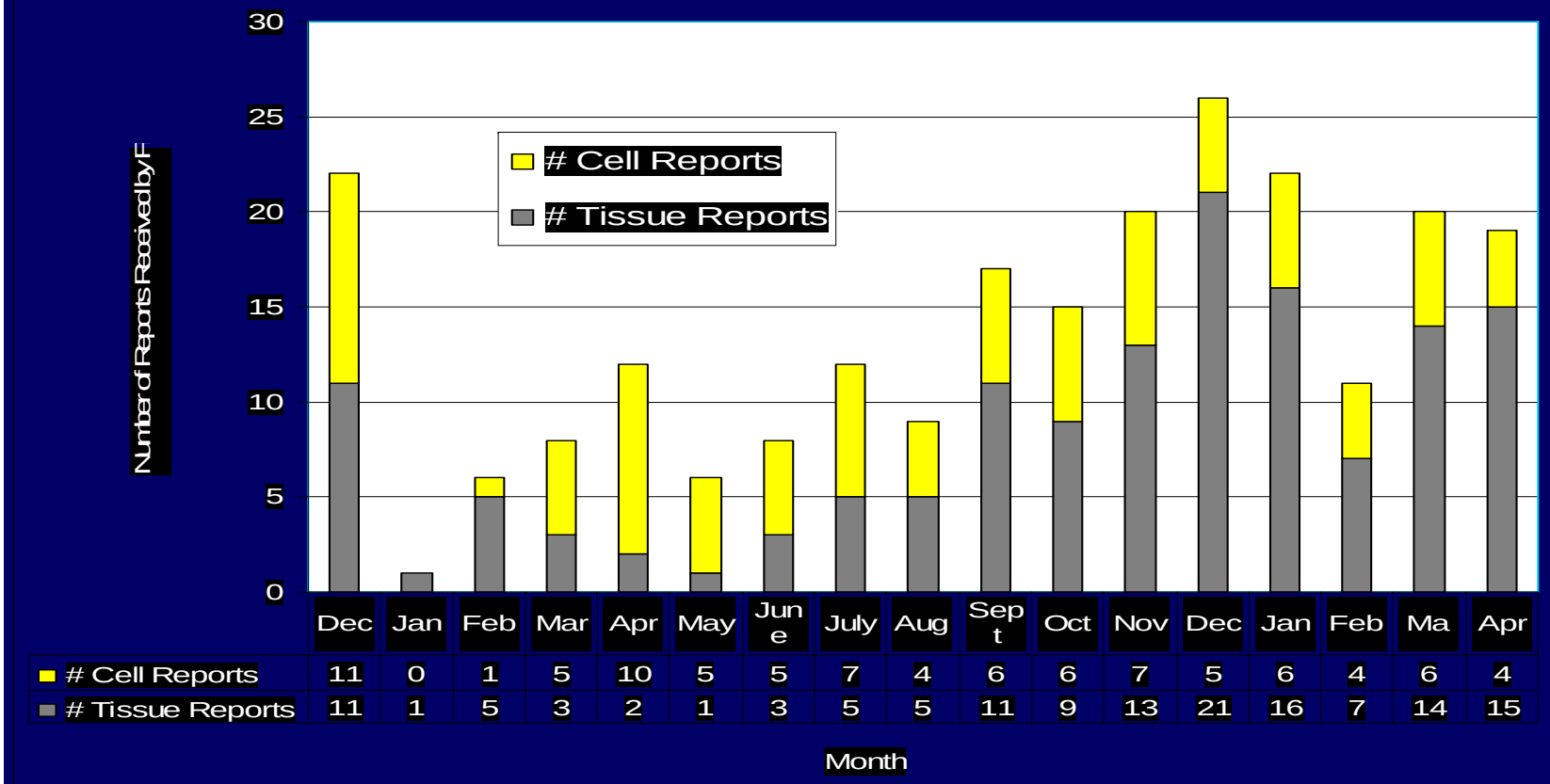
CBER's TST Follow-up on MedWatch Reports

- Occurs if report indicates an infectious disease transmission or possible transmission that may be associated with an HCT/P
- Involves gathering information from reporter or manufacturer, as indicated
- Tries to determine if the infection was transmitted by the tissue (difficult to determine in most cases)

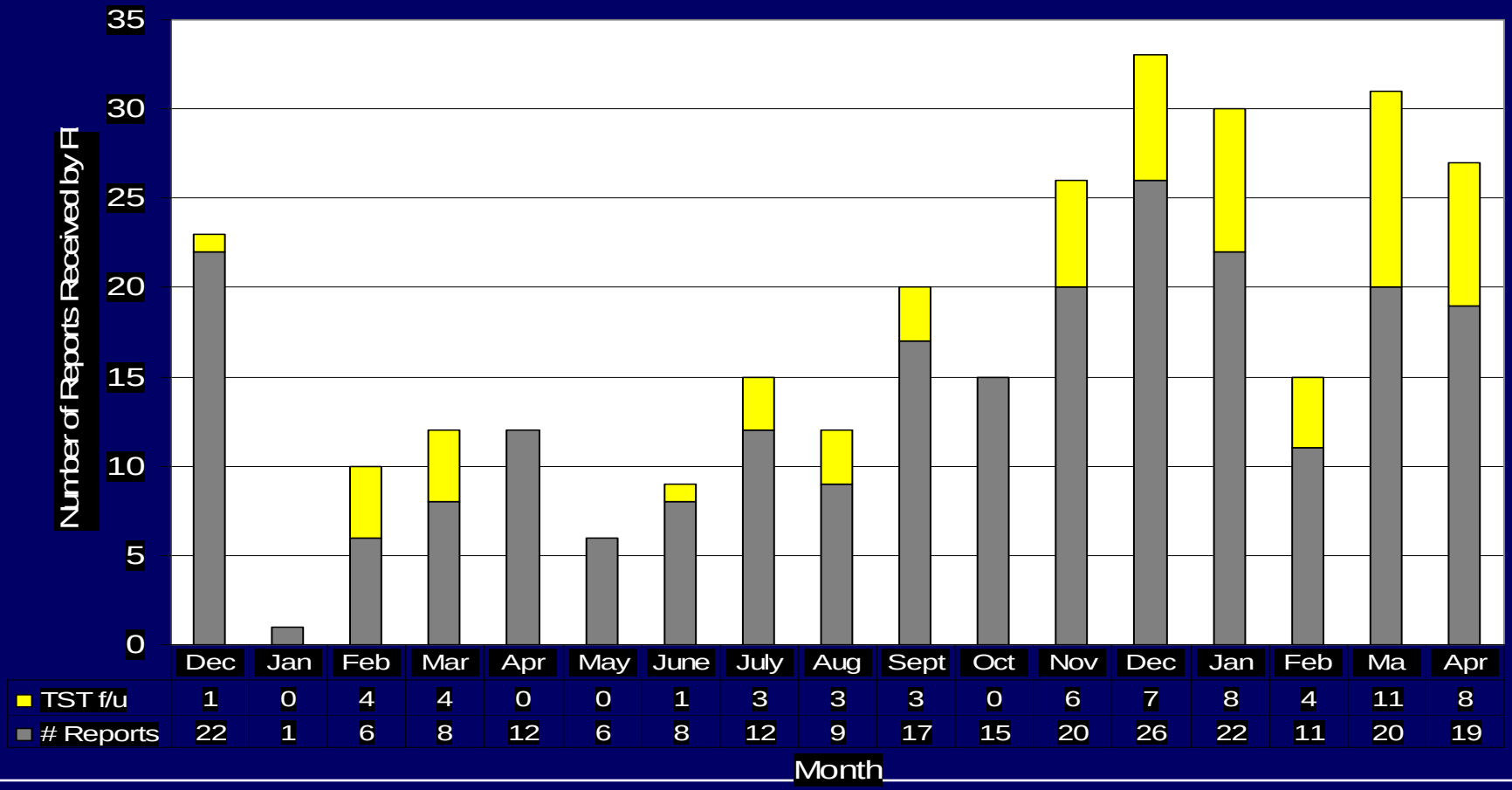
TST to Date

- Guidance for Industry: Medwatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to HCT/Ps: 11/30/2005
- CBER SOPP 8508: Procedures for Handling Adverse Reaction Reports Related to “361” HCT/Ps, 11/28/2005
- Developed Database for HCT/P Medwatch reports and follow-ups
- Additional information at http://www.fda.gov/cber/tissue/hctadverse.htm
- Approximately 70 follow-ups to date

HCT/P Medwatch Reports Received by FDA 12/04-04/06



TST Follow-ups (12/04-4/06)



Adverse Reaction Reporting and HCT/P Safety

- Required reporting for HCT/P manufacturers
- With MedWatch, FDA can detect trends across the country that may not be identified at an individual site
- Goal of HCT/P surveillance is to prevent additional adverse reactions

U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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